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10/574,645	08/10/2006	David Salomon	251206	9318

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EXAMINER	
POHNERT, STEVEN C	

ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Attachment to Advisory

Continuation of box 11:

The response asserts that the amended claims have overcome the enablement rejection of record.

The response on page 6 asserts that the specification in paragraph 19 teaches, "that a control sample contains genomic DNA of a mammal that is not known to have a neurodegenerative disease." The response further assert that the specification teaches in example 1 teaches the use of controls. These arguments have been thoroughly reviewed but are not considered persuasive as the claims are drawn to a control sample, the cited portion of paragraph 19 suggests that the control sample have genomic DNA from a mammal known not to have neurodegenerative disease, but does not require that the sample come from the central nervous system, thus it is unpredictable to compare gene expression from different tissues. Further the response appears to be asserting paragraph 19 is a limiting definition and in such the suggested definition of paragraph 19 is of different scope than the claimed invention as the claims are drawn to expression and a sample of genomic DNA for a mammal known not to have a neurodegenerative disease would not allow determination of expression. Further the teachings of example 1 do not look at expression or define that a control sample is of the central nervous system, thus it does not overcome the issue of unpredictability of diagnosis by expression in which expression is compared between different tissues or even different species.

The response further notes that the applicant is not required to provide working examples to establish enablement of an invention. The response further asserts that the office has not provided support for the conclusion that the artisan would not be able to predictably carry out the instant method in humans. These arguments have been thoroughly reviewed but are not considered persuasive as first the claims do not require comparison of expression from samples of the same tissue as discussed above, making them unpredictable. Further the claims as presented do not require comparison of expression from mammals of the same species. Further the office in the response to argument in the office action presented the teachings of Ragahavan and Enard. Ragahavan teaches that different viruses (SIV and SHIV) have different pathologies in the induction of NeuroAIDS. Enrad teaches that there is variation in neural gene expression between primates, thus it would be unpredictable to associate altered expression of a single gene in a primate species with diagnosis in other species without specific guidance. Thus contrary to the assertion of the response the office has presented a supported argument to the unpredictability in humans. Further the claims as presented are not limited to either humans or primates, but any mammal.

The response notes, "The Office is reminded that the applicant does not have to prove that a correlation exists between a particular activity and an asserted use of a compound as a matter of statistical certainty." This is a spurious argument as the claims are not drawn to an asserted use of a compound and a particular activity. The claims are drawn to diagnosis based on increased expression, which is different. The response further asserts the office has raised concerns regarding normalization of gene

expression with a specific phenotype, but has provided no specific evidence of the unpredictability of the claimed invention. These arguments have been thoroughly reviewed but are not considered persuasive as the variability in gene expression and phenotype demonstrate that comparison of a single sample to a single control sample is not predictability due to the variability associated with gene expression analysis. Further the claims do not require comparison to a sample of the same tissue or species.

The response further asserts that the isolated example of the teachings of Ragahavan of species specific differences in HIV infection in Macaques does not take away from other reports of brain histopathology resulting from SIV infection and brain histopathology disclosed in paragraph 69 of the disclosure. These arguments have been thoroughly reviewed but are not considered persuasive first as the response is mischaracterizing Ragahvan. Ragahavan teaches infection with SHIV and SIV result in different pathologies, not HIV as asserted. Further the response appears to be asserting that the specification and prior art suggest there is similar pathologies across species. First, MPEP 716.01(c) makes clear that "The arguments of counsel cannot take the place of evidence in the record. In re Schulze , 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long - felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant." Here, the statements suggesting similar pathologies across species is not

supported by evidence. The teachings in paragraph 69 of the disclosure describe that astrocyte activation and pathology are similar in SIV infected macaque and presumably HIV humans, not pathophysiology in general.

This should not be construed as an invitation for providing evidence. As further stated in the MPEP 716.01 regarding the timely submission of evidence:

A) Timeliness.

Evidence traversing rejections must be timely or seasonably filed to be entered and entitled to consideration. In re Rothermel, 276 F.2d 393, 125 USPQ 328 (CCPA 1960). Affidavits and declarations submitted under 37 CFR 1.132 and other evidence traversing rejections are considered timely if submitted:

(1) prior to a final rejection,

(2) before appeal in an application not having a final rejection, or

(3) after final rejection and submitted

(i) with a first reply after final rejection for the purpose of overcoming a new ground of rejection or requirement made in the final rejection, or

(ii) with a satisfactory showing under 37 CFR 1.116(b) or 37

CFR 1.195, or

(iii) under 37 CFR 1.129(a).

Thus for the reasons presented above the enablement rejection of claims 1, and 17-20 is maintained.

Conclusions

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven C. Pohnert whose telephone number is 571-272-3803. The examiner can normally be reached on Monday-Friday 6:30-4:00, every second Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Steven Pohnert

/Sarae Bausch/
Primary Examiner, Art Unit 1634